REMARKS

I. Status of the Claims

Claims 1, 3-6 and 8-13 are pending in the application. In response to the restriction requirement which the examiner imposed, applicants elected Group II, claims 3-5 and 10. Thus, claims 1, 6, 8, 9 and 11-13 stand withdrawn. Claims 3-5 and 10 stand rejected, variously, under 35 U.S.C. §112, second paragraph, 35 U.S.C. §102 and 35 U.S.C. §103. The specific grounds for rejection, and applicants' response thereto, are set out in detail below.

II. Objections

The examiner has objected to the form of trademark usage. Amendments have been provided. The examiner has also cautioned against the use of hyperlinks. The specification was reviewed, and no hyperlinks were found. Reconsideration and withdrawal of the objections is therefore respectfully requested.

III. Rejection Under 35 U.S.C. §112, Second Paragraph

Claims 3-5 and 10 are rejected under the second paragraph of §112 as indefinite. Applicants traverse, but in the interest of advancing the prosecution, claim 4 has been amended. It is believed that the amendment overcomes the rejection, and therefore reconsideration and withdrawal of the rejection is respectfully requested.

IV. Rejection Under 35 U.S.C. §102

Claims 4 and 10 are rejected as anticipated by Allison. Applicants traverse.

First, applicants point out that the claims have been amended to recite prevention of plaque rupture, which is distinct from the alleged teachings of Allison, which deal with treating patients at risk of thrombosis. Although thrombosis can follow, as a downstream effect of plaque rupture, the rupture of an atherosclerotic plaque and the formation of thrombus are two ***entirely separate*** physiological events, involving totally different factors. Moreover, plaque rupture is just one of a multitude of upstream events that can cause thrombosis.

Second, applicants point out that Allison teaches that annexins are anti-thrombotic because they are said to bind phosphatidylserine that is accessible on the surface of activated platelets, and thus block the ability of activated platelets to interact, via phosphatidylserine, with tissue factors required for the coagulation of blood. Please see Allison at page 4, line 22 to page 5, line 20. This is particularly true of Annexin V. Thus, Allison teaches that Annexin V interacts directly with a ***developing*** thrombus to prevent ***further*** recruitment of coagulation factors to it, thus stopping the growth of the thrombus, and in particular, stopping amplified platelet aggregation. Please see Allison at page 5, lines 30-31. Again, this is distinct from the events that give rise to rupture of an atherosclerotic plaque.

Turning to the specifics of the reference, there is nothing to teach that Annexin V has the ability to modulate activities other than thrombus formation, much less that it could specifically prevent the rupture of atherosclerotic plaques:

> Page 7, lines 13-16: this passage teaches only that Annexin V may be useful in preventing arterial or venous thrombosis;
>
> Page 8, lines 8-12: this passage teaches that Annexin V can be administered to a subject at risk of thrombosis, and so can be administered after arterial thrombosis such as coronary, cerebral or transient cerebral thrombosis, or after a surgical operation

associated with venous thrombosis, or in subjects that have diabetes, are pregnant or have parturition;

Page 29, lines 15-24: this passage refers to treatment of arterial or venous thrombosis "caused by any medical procedure or condition";

Page 30, lines 7-9: this passage refers merely to administration of Annexin V "after thrombosis to prevent further thrombosis or under conditions in which the subject is susceptible to or at risk of thrombosis."

None of these disclosures teach or suggest that Annexin V could impact atherosclerotic plaque rupture.

Given the limitation of claim 4 as presented for reconsideration, and the aforementioned restrictions on the Allison teachings, applicants submit that the cited reference cannot be deemed anticipatory of the present claims. Reconsideration and withdrawal of the rejection is therefore respectfully requested.

V. Rejection Under 35 U.S.C. §103

Claims 3-5 are rejected as rendered obvious by Allison in view of Pamuk *et al.* Once again, applicants traverse.

As discussed above, Allison does not teach or suggest the use of Annexin V to prevent plaque rupture. Rather, the person skilled in the art, in light of the teaching of Allison, would only consider using Annexin V to deal with one of the downstream ***effects*** of plaque rupture, *i.e.*, dealing directly with thrombus formation. Therefore, a person skilled in the art would not consider it obvious to use Annexin V in an attempt to prevent plaque rupture.

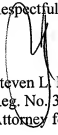
Pamuk *et al.* does not address (nor was it cited to address) the deficiency in Allison vis-à-vis claim 4 as amended, which is directed to the prevention of plaque rupture. Pamuk *et al.* is cited by the examiner only as alleged evidence that atherothrombosis was known to be common in SLE patients. This does not lead the reader of Allison to have any expectation that Annexin V would be able to prevent plaque rupture. In fact, Pamuk says nothing about Annexin V at all, much less that it could have alternative biological effects to those described in Allison. Therefore, even if the skilled person ***did*** combine Allison and Pamuk *et al.*, there would still be no suggestion or expectation that Annexin V could prevent plaque rupture, whether in an SLE patient or any other individual.

Therefore, for these reasons, the claims are also non-obvious in view of the combination of Allison and Pamuk *et al.* Reconsideration and withdrawal of the rejection is therefore respectfully requested.

VI. Conclusion

In light of the foregoing, applicants respectfully submit that all claims are in condition for allowance, and an early notification to that effect is earnestly solicited. Should the examiner have any questions regarding this response, a telephone call to the undersigned is invited.

Respectfully submitted,



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